



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/247,874

Applicant(s)

Duff et al

Examiner

Richard Schnizer

Art Unit

1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Mar 21, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Mar 2, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: Amended claim 1 alters the scope of the claim to include all inflammatory diseases, rather than diseases caused by overproduction of IL-1B. This raises new issues requiring further search and consideration.

4. ☒ Applicant's reply has overcome the following rejection(s):
None. See attached.
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because:

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: _____
Claim(s) objected to: _____
Claim(s) rejected: 1-14 and 34-44
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

Art Unit: 1632

ADVISORY ACTION

Applicants request for reconsideration has been considered but does not place the application in condition for allowance.

Rejections for New Matter, Indefiniteness, Anticipation, and Obviousness

Applicants proposed amendment and declaration by Dr. di Giovine would be sufficient to overcome the rejection of claims 1-14, 35, 36, 43, and 44 under 35 USC 112, first paragraph for the introduction of new matter, the rejection of claims 35 and 36 under 35 USC 112, second paragraph, the rejection of claim 34 under 35 USC 102, and the rejections of claims 35 and 36 under 35 USC 103. However, the amendment was not entered for the reasons given below.

Enablement

Applicant argues that the specification provides evidence that overexpression of IL-1B is linked to many diseases.

In response, the Examiner points out that the claims require that the diseases must be caused or contributed to by IL-1B overexpression, not merely associated with IL-1B overexpression. The specification has established a correlation between several diseases and a specific haplotype (33221461) which comprises several alleles of the IL-1 gene cluster, including IL-1B, but has failed to show that any disease is caused or contributed to by IL-1B overexpression. The prior art teaches that identification of mutations in the IL-1 cluster should

Art Unit: 1632

"allow the investigator to begin to determine which of the alleles are causative, rather than merely linked to a disease-causing allele." See page 13, lines 16-18 of WO 98/54359. Thus at the time of the invention, no biochemical linkage between IL-1 beta overexpression and any disease had been established. For this reason, the response fails to overcome the standing rejection.

Applicants proposed amendments to the claims in Paper No. 15 would overcome the grounds for this enablement rejection, however these amendments have not been entered because they alter the scope of the claims. The original claims were drawn to methods of determining susceptibility to diseases which are "caused or contributed to by an inappropriately high level of IL-1B". In contrast the amended claims are drawn to methods of determining susceptibility to any inflammatory disease. This alteration in scope would require further search and consideration.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 103-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Patsy Zimmerman whose telephone number is 703-308-8338.

Richard Schnizer, Ph.D.

Karen M. Hauda
KAREN M. HAUDA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600